1647

Docket No.: CIBT-P01-058
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Lu et al.

Application No.: 09/499526 Confirmation No.: 1398

Filed: February 10, 2000 Art Unit: 1647

For: METHODS AND REAGENTS FOR TREATING GLUCOSE METABOLIC DISORDERS Examiner: R. M. Deberry

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Supplemental Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Supplemental Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Supplemental Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 18-1945 in the amount of $180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. CIBT-P01-058. A duplicate copy of this paper is enclosed.

Dated: 9/19/05

Respectfully submitted,

By 

Melissa S. Rones, Ph.D.
Registration No.: 54,408
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant

PTO/SB/17 (12-04v2)
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FEE TRANSMITTAL
For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 180.00

Complete if Known	
Application Number	09/499526
Filing Date	February 10, 2000
First Named Inventor	Kuanghui Lu
Examiner Name	R. M. Deberry
Art Unit	1647
Attorney Docket No.	CIBT-P01-058

METHOD OF PAYMENT (check all that apply)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- =	_____	x _____	=	_____

Multiple Dependent Claims: Fee ($) _____ Fee Paid ($) _____

Indep. Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- =	_____	x _____	=	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

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4. OTHER FEE(S) **Fees Paid ($)**

Non-English Specification, $130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 54,408	Telephone (617) 951-7653
Name (Print/Type)	Melissa S. Rones, Ph.D.		Date 9/19/05

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PTO/SB/92 (09-04)
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Application No. (if known): 09/499526 Attorney Docket No.: CIBT-P01-058

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IDS by Applicant – Form PTO/SB/08 (79 References)
References 79, CN2-CN5

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Sheet 1 of 5

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Examiner Name	R. M. Deberry
Attorney Docket Number	CIBT-P01-058

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CN2	Ando, R.; et al., "Feeding responses to several neuropeptide Y receptor agonists in the neonatal chick," Eur J Pharmacol., 427(1):53-59 (2001).	
	CO2	Andres, C. J., et al., "Differentially functionalized diamines as novel ligands for the NPY_2 receptor," Bioorg Med Chem Lett., 13(17):2883-2885 (2003).	
	CP2	Bader, R., et al., "Key Motif to Gain Selectivity at the Neuropeptide Y_5-Receptor: Structure and Dynamics of Micelle-Bound [Ala^{31}, Pro^{32}]-NPY," Biochemistry, 41(25):8031-8042 (2002).	
	CQ2	Balasubramaniam, A., et al., "Structure-activity studies of peptide YY(22-36): N-α-Ac-[Phe^{27}]PYY(22-36), a potent antisecretory peptide in rat jejunum," Peptides, 14(5):1011-1016 (1993).	
	CR2	Balasubramaniam, A., et al., "Synthesis of neuropeptide Y," Int J Pept Protein Res., 29(1):78-83 (1987).	
	CS2	Balasubramaniam, A., et al., "Syntheses and Receptor Affinities of Partial Sequences of Peptide YY (PYY)," Peptide Research, 1(1):32-35 (1988).	
	CT2	Balasubramaniam, A., et al., "Bis(31/31'){[Cys^{31}, Nva^{34}]NPY(27-36)-NH_2}: a neuropeptide Y (NPY) Y_5 receptor selective agonist with a latent stimulatory effect on food intake in rats," Peptides, 23(8):1485-1490 (2002).	
	CU2	Balasubramaniam, A., "Neuropeptide Y Family of Hormones: Receptor Subtypes and Antagonists," Peptides, 18(3):445-457 (1997).	
	CV2	Beck, A., et al., "Highly potent and small neuropeptide Y agonist obtained by linking NPY 1-4 via spacer to α-helical NPY 25-36," FEBS Lett., 244(1):119-122 (1989).	
	CW2	Beck-Sickinger, A. G., et al., "Cyclopeptide analogs for characterization of the neuropeptide Y Y_2-receptor," J Recept Res., 13(1-4):215-228 (1993).	
	CX2	Berglund, M. M., et al., "Recent Developments in Our Understanding of the Physiological Role of PP-Fold Peptide Receptor Subtypes," Exp Biol Med (Maywood), 228(3):217-244 (2003).	
	CY2	Bischoff, A. and Michel, M. C., "Emerging functions for neuropeptide Y_5 receptors," Trends Pharmacol Sci., 20(3):104-106 (1999).	

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	2	of	5

Complete if Known	
Application Number	09/499526
Filing Date	February 10, 2000
First Named Inventor	Kuanghui Lu
Art Unit	1647
Examiner Name	R. M. Deberry
Attorney Docket Number	CIBT-P01-058

	CZ2	Boublik, J. H., et al., "Synthesis and hypertensive activity of neuropeptide Y fragments and analogues with modified N- or C-termini or D-substitutions," J Med Chem, 32(3):597-601 (1989).	
	CA3	Cabrele, C. and Beck-Sickinger, A. G., "Molecular characterization of the ligand-receptor interaction of the neuropeptide Y family," J Pept Sci., 6(3):97-122 (2000).	
	CB3	Cabrele, C., et al., "The first selective agonist for the neuropeptide YY_5 receptor increases food intake in rats," J Biol Chem., 275(46): 36043-36048 (2000).	
	CC3	Cabrele, C., et al., "Ala^{31}-Aib^{32}: Identification of the key motif for high affinity and selectivity of neuropeptide Y at the Y_5-receptor," Biochemistry, 41(25):8043-8049 (2002).	
	CD3	Cabrele, C., et al., "Y-receptor affinity modulation by the design of pancreatic polypeptide/neuropeptide Y chimera led to Y_5-receptor ligands with picomolar affinity," Peptides, 22(3):365-378 (2001).	
	CE3	Chen, Z., et al., "Ser^{13}-phosphorylated PYY from porcine intestine with a potent biological activity," FEBS Lett., 492(1-2):119-122 (2001).	
	CF3	Conlon, J. M., "The origin and evolution of peptide YY (PYY) and pancreatic polypeptide (PP)," Peptides, 23(2):269-278 (2002).	
	CG3	Corp, E. S., et al., "Feeding after fourth ventricular administration of neuropeptide Y receptor agonists in rats," Peptides, 22(3):493-499 (2001).	
	CH3	Cox, H. M., et al., "Structure-activity relationships with neuropeptide Y analogues: a comparison of human Y_1-, Y_2- and rat Y_2-like systems," Regulatory Peptides, 75-76:3-8 (1998).	
	CI3	Dumont, Y., et al., "Evaluation of truncated neuropeptide Y analogues with modifications of the tyrosine residue in position 1 on Y_1, Y_2 and Y_3 receptor sub-types," Eur J Pharmacology, 238(1):37-45 (1993).	
	CJ3	Eto, B., et al., "Effects of Peptide YY and Its Analogues on Chloride Ion Secretion in Fed and Fasted Rat Jejunum," Peptides, 16(8):1403-1409 (1995).	
	CK3	Fackelmann, K., "Gut hormone could curb urge to overeat", USA Today.com (Aug 7 2002)	
	CL3	Feinstein, R. D., et al., "Structural Requirements for Neuropeptide Y^{18-36}-Evoked Hypotension: A Systematic Study," J Med Chem., 35(15):2836-2843 (1992).	
	CM3	Fournier, A., et al., "Conformational and Biological Studies of Neuropeptide Y Analogs Containing Structural Alterations," Mol Pharmacol., 45(1):93-101 (1994).	
	CN3	Gobbi, M., et al, "Autoradiographic Reevaluation of the Binding Properties of ^{125}I-[Leu^{31},Pro^{34}]Peptide YY and ^{125}I-Peptide YY_{3-36} to neuropeptide Y Receptor Subtypes in Rat Forebrain," J Neurochem., 72(4):1663-1670 (1999).	
	CO3	Gordon, E. A., et al., "Centrally truncated neuropeptide Y analog acts as an agonist for Y1 receptors on SK-N-MC cells," Neuroscience Letters, 119(2):187-190 (1990).	
	CP3	Grundemar, L., et al., "Ligand binding and functional effects of systematic double D-amino acid residue substituted neuropeptide Y analogs on Y1 and Y2 receptor types," Regulatory Peptides, 62(2-3):131-136 (1996).	
	CQ3	Halatchev, I. G., et al., "Peptide YY_{3-36} Inhibits Food Intake in Mice through a Melanocortin-4 Receptor-Independent Mechanism," Endocrinology, 145(6):2585-2590 (2004).	
	CR3	Henry, M., et al., "Energy Metabolic Profile of Mice after Chronic Activation of Central NPY Y1, Y2, or Y5 Receptors," Obesity Research 13(1):36-47 (2005).	
	CS3	Hu, Y., et al., "Identification of a Novel Hypothalamic Neuropeptide Y Receptor Associated with Feeding Behavior," J Biol Chem., 271(42):26315-26319 (1996).	
	CT3	Inui, A., "Neuropeptide Y feeding receptors: are multiple subtypes involved?" Trends Pharmacol Sci., 20(2):43-46 (1999).	
	CU3	Kanatani, A., et al., "L-152,804: Orally active and selective neuropeptide Y Y5 receptor antagonist," Biochemical Biophysical Research Communications, 272(1):169-173 (2000).	

Examiner Signature		Date Considered	

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Sheet	3	of	5

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Filing Date	February 10, 2000
First Named Inventor	Kuanghui Lu
Art Unit	1647
Examiner Name	R. M. Deberry
Attorney Docket Number	CIBT-P01-058

	CV3	Kanatani, A., et al., "The novel neuropeptide Y Y_1 receptor antagonist J-104870: a potent feeding suppressant with oral bioavailability," Biochem Biophys Res Commun., 266(1):88-91 (1999).	
	CW3	Keire, D. A., et al., "Structure and receptor binding of PYY analogs," Peptides, 23(2):305-321 (2002).	
	CX3	Keire, D. A., et al., "Solution structure of monomeric peptide YY supports the functional significance of the PP-fold," Biochemistry, 39(32):9935-9942 (2000).	
	CY3	Keire, D. A., et al., "Primary structures of PYY, [Pro^{34}] PYY, and PYY-(3-36) confer different conformations and receptor selectivity," Am J Physiol. Gastrointest Liver Physiol, 279(1):G126-G131 (2000).	
	CZ3	Kirby, D. A., et al., "Neuropeptide Y: Y_1 and Y_2 affinities of the complete series of analogues with single D-residue substitutions," J Med Chem., 36(24):3802-3808 (1993).	
	CA4	Kirby, D. A., et al., "Y_1 and Y_2 receptor selective neuropeptide Y analogues: evidence for a Y_1 receptor subclass," J Med Chem., 38(22):4579-4586 (1995).	
	CB4	Krstenansky, J. L., et al., "Centrally truncated and stabilized porcine neuropeptide Y analogs: design, synthesis, and mouse brain receptor binding," Proc Natl Acad Sci U S A., 86(12):4377-4381 (1989).	
	CC4	Krstenansky, J. L., et al., "C-terminal modifications of neuropeptide Y and its analogs leading to selectivity for the mouse brain receptor over the porcine spleen receptor," Neuropeptides, 17(3):117-120 (1990).	
	CD4	Leban, J. J., et al., "Novel modified carboxy terminal fragments of neuropeptide Y with high affinity for Y_2-type receptors and potent functional antagonism at a Y_1-type receptor," J Med Chem., 38(7):1150-1157 (1995).	
	CE4	Liu, C. D., et al., "Synthetic peptide YY analog binds to a cell membrane receptor and delivers fluorescent dye to pancreatic cancer cells," J Gastrointest Surg., 5(2):147-152 (2001).	
	CF4	Lundell, I., et al., "Cloning of a human receptor of the NPY receptor family with high affinity for pancreatic polypeptide and peptide YY," J Biol Chem., 270(49):29123-29128 (1995).	
	CG4	Makimura, H., et al., Obesity Poster Abstract No. 118 "Adrenalectomy stimulates hypothalamic Proopiomelanocortin mRNA but does not correct obesity in diet-iduced obese mice."	
	CH4	Markison S., et al., Obesity Poster Abstract No. 119 "Selective melanin-concentrating hormone receptor antagonists decrease feeding in rodents."	
	CI4	Martin, N. M., et al., "Pre-obese and obese agouti mice are sensitive to the anorectic effects of peptide YY_{3-36} but resistant to ghrelin," Int J Obes Relat Metab Disord., 28(7):886-893 (2004).	
	CJ4	Mashiko, S., et al., "Characterization of neuropeptide Y (NPY) Y5 receptor-mediated obesity in mice: chronic intracerebroventricular infusion of D-Trp^{34}NPY," Endocrinology, 144(5):1793-1801 (2003).	
	CK4	Mashiko, S., et al., Obesity Poster Abstract No. 120 "Characterization of neuropeptide Y Y5 receptor mediated obesity in mice"	
	CL4	Mullins, D., et al., "Identification of potent and selective neuropeptide Y Y_1 receptor agonists with orexigenic activity in vivo," Molecular Pharmacology, 60(3):534-540 (2001).	
	CM4	Murakami, Y., et al., "1,3-Disubstituted benzazepines as novel, potent, selective neuropeptide Y Y1 receptor antagonists," J Med Chem., 42(14):2621-2632 (1999).	
	CN4	Murase, S., et al., "Acylation of the α-amino group in neuropeptide Y(12-36) increases binding affinity for the Y_2 receptor," J Biochem (Tokyo), 119(1):37-41 (1996).	
	CO4	Parker, E. M., et al., "GR231118 (1229U91) and other analogues of the C-terminus of neuropeptide Y are potent neuropeptide Y Y_1 receptor antagonists and neuropeptide Y Y_4 receptor agonists," Eur J Pharmacol., 349(1):97-105 (1998).	
	CP4	Parker, E. M., et al., "[D-Trp^{34}] neuropeptide Y is a potent and selective neuropeptide Y Y_5 receptor agonist with dramatic effects on food intake," Peptides, 21(3):393-399 (2000).	

Examiner Signature		Date Considered	

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	CQ4	Parker, S. L. and Parker, M. S., "FMRFamides exert a unique modulation of rodent pancreatic polypeptide sensitive neuropeptide Y (NPY) receptors," Can J Physiol Pharmacol., 78(2):150-161 (2000).	
	CR4	Potter, E. K., et al., "A novel neuropeptide Y analog, *N*-acetyl [Leu^{28},Leu^{31}]neuropeptide Y-(24-36), with functional specificity for the presynaptic (Y_2) receptor," Eur J Pharmacol., 267(3):253-262 (1994).	
	CS4	Renshaw, D. and Batterham, R. L., "Peptide YY: A Potential Therapy for Obesity," Curr Drug Targets, 6(2):171-179 (2005).	
	CT4	Rico, L., et al., Obesity Poster Abstract No. 117 "Early and dissociated leptin and insulin resistance in transgenic mice overexpressing leptin from keratinocytes."	
	CU4	Rist, B., et al., "The bioactive conformation of neuropeptide Y analogues at the human Y_2-receptor," Eur J Biochem., 247(3):1019-1028 (1997).	
	CV4	Rist, B., et al., "Modified, cyclic dodecapeptide analog of neuropeptide Y is the smallest full agonist at the human Y_2 receptor," FEBS Lett., 394(2):169-173 (1996).	
	CW4	Sato, N., et al., "Design and Synthesis of the Potent, Orally Available, Brain-Penetrable Arylpyrazole Class of Neuropeptide Y5 Receptor Antagonists," J Med Chem., 46(5):666-669 (2003).	
	CX4	Servin, A. L., et al., "Peptide-YY and Neuropeptide-Y Inhibit Vasoactive Intestinal Peptide-Stimulated Adenosine 3',5'-Monophosphate Production in Rat Small Intestine: Structural Requirements of Peptides for Interacting with Peptide-YY-Preferring Receptors," Endocrinology, 124(2):692-700 (1989).	
	CY4	Shan, L., et al., "Structural Basis for Gluten Intolerance in Celiac Sprue," Science, 297(5590):2275-2279 (2002).	
	CZ4	Sheikh, S. P., "Neuropeptide Y and peptide YY: major modulators of gastrointestinal blood flow and function," Am J Physiol., 261(5 Pt 1):G701-G715 (1991).	
	CA5	Silva, A. P., et al., "Neuropeptide Y and its receptors as potential therapeutic drug targets," Clinica Chimica Acta, 326(1-2):3-25 (2002).	
	CB5	Small, C. J., et al., "Peptide analogue studies of the hypothalamic neuropeptide Y receptor mediating pituitary adrenocorticotrophic hormone release," Proc Natl Acad Sci U S A., 94(21):11686-11691 (1997).	
	CC5	Soll, R. M., et al., "Novel analogues of neuropeptide Y with a preference for the Y_1-receptor," Eur J Biochem., 268(10):2828-2837 (2001).	
	CD5	Tatemoto, K., et al., "Synthesis of receptor antagonists of neuropeptide Y," Proc Natl Acad Sci U S A.,89(4):1174-1178 (1992).	
	CE5	Thum, A., et al., "Endoproteolysis by isolated membrane peptidases reveal metabolic stability of glucagon-like peptide-1 analogs, exendins-3 and -4," Exp Clin Endocrinol Diabetes, 110(3):113-118 (2002).	
	CF5	Totheroh, G., "Science Offers Promising Treatment for an Overweight Nation" CBN News (Sept 4, 2003).	
	CG5	Tschop, M., et al., "Physiology: does gut hormone PYY3-36 decrease food intake in rodents? Nature. 2004 Jul 8; 430(6996):1 p following 165; discussion 2 p following 165.	
	CH5	Tseng, W. W. and Liu, C. D., "Peptide YY and cancer: current findings and potential clinical applications," Peptides, 23(2):389-395 (2002).	
	CI5	Turnbull, A. V., et al., "Selective antagonism of the NPY Y5 receptor does not have a major effect on feeding in rats," Diabetes, 51(8):2441-2449 (2002).	
	CJ5	Walker, M. W., et al., "Neuropeptide Y modulates neurotransmitter release and Ca^{2+} currents in rat sensory neurons," J Neurosci., 8(7):2438-2446 (1988).	
	CK5	Walker, M. W., et al., "A structure-activity analysis of the cloned rat and human Y4 receptors for pancreatic polypeptide," Peptides, 18(4):609-612 (1997).	

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	CL5	Weinberg, D. H., et al., "Cloning and expression of a novel neuropeptide Y receptor," J Biol Chem., 271(28):16435-16438 (1996).	
	CM5	Wilding, J. P., "Neuropeptides and appetite control," Diabet Med., 19(8):619-627 (2002).	
	CN5	HYPERDICTIONARY definition of "Structure Activity Relationship"	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	